UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF NEW YORK

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TYLER WOOD, Plaintiff

vs.

MEDTRONIC, INC., Defendant.

- - - - - - - - - - - - - - -X

14-CV-6298(CJS)

Rochester, New York
September 10, 2015
2:01 p.m.

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE CHARLES J. SIRAGUSA
UNITED STATES DISTRICT JUDGE

THOMAS J. RZEPKA, ESQ.
28 East Main Street
Suite 900
Lewiston, New York 14092
Appearing on behalf of the Plaintiff

MAYER BROWN, LLP
BY: ANDREW E. TAUBER, ESQ.
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Appearing on behalf of the Defendant

AUDIO RECORDER: Kathy Allen

TRANSCRIBER: Christi A. Macri, FAPR-CRR
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Rochester, New York 14614

(Proceedings recorded by electronic sound recording, transcript produced by computer).

P R O C E E D I N G S

* * *

THE COURT: And Mr. Tauber on behalf of Medtronic, Inc.

Counsel, we're here on the motion by Medtronic. Counsel, you can have a seat.

Now, this has an interesting procedural history. I've got it here. The action was removed to federal court on May 30th of 2014, based on diversity.

Because there was no activity in the case, on November 10th of 2014, the Court issued an Order to Show Cause why the action should not be dismissed for failure to prosecute.

Then, Mr. Rzepka, you responded on November 25th, 2014, requesting the Court not dismiss the action. While you didn't explicitly explain the lack of activity, you mentioned that there was a separate -- you referred to it as a parallel products liability action in New York State Supreme Court against the manufacturer, like a Big Wheels your client was riding back when he was, I think, 8 years old and required his initial spinal surgery, and explained that eventually the rod that was placed in fractured, he needed further surgery and that's when they -- the product at issue, the infusion, was necessitated with respect to the bone graft.

But then the defendant filed a motion on

January 30th, 2015, to dismiss the action, and we issued a scheduling order that required you to file opposing papers by March 13th, and gave the defendant a chance to file a response on April 3rd, and that's when a lot occurred.

On April 3rd, you contacted -- you sent a letter to the Court requesting additional time.

At the time we were una -- we hadn't received the reply or we hadn't -- it wasn't filed, but we weren't aware of the reply and believed that you were requesting additional time to file your responding papers within the time that we granted, but that was not the case.

The time for you to file had expired. Mr. Kehoe sent you an e-mail indicating that, you know, you need to -- and in your letter you didn't really explain any reason why you were asking for additional time.

Mr. Kehoe sent you a letter asking you to give us -- put how much additional time you needed. That's when the defense responded and said they were opposing any additional time explaining that you're outside the Court's scheduling order.

But, in any event, you didn't really even reply to Mr. Kehoe's e-mail for an additional month, and we issued a -- based on all that, we issued this Decision and Order of May 18th, 2016 (sic) denying additional time and denying consideration of your opposing papers, including your

application to file an amended complaint.

So that's the procedural posture. It's confusing -- I'm confused by the fact why that the case was removed on May 30th of 2014, and no answer was ever served.

Is that correct, Mr. Tauber?

MR. TAUBER: That's correct, Your Honor.

THE COURT: No answer was served why you didn't seek default and then move for a default judgment because at least had that application been made, everything probably would have moved along, according to Hoyle.

But it is what it is. It appears from the pleading that we have to deal with, and that is the complaint that was -- that was originally filed, you're making allegations -- in paragraph 8 you say that the bone graft was defectively designed and manufactured and the defendants failed to warn the plaintiff and others of dangers associated with using the bone graft, especially in off-label cervical spines.

Again, apparently -- but looking at the materials before the Court, it appears that the material at issue was approved by the FDA for use in lumbar spine grafts, but it also appeared there was a warning that it shouldn't be used with children. And at least a caution for using it in the cervical spine.

Now, I understand, at least I'm learning, that that

doesn't mean it's -- you couldn't use it, but I don't know why -- I assume there's -- was there an action filed against the doctor who utilized this procedure? I mean, if the doctor -- I don't understand. Apparently, the doctor who performed the procedure -- you don't have to -- I appreciate you standing up, but you don't have to because the mics are on.

But it's just a little confusing to me because why would a doctor -- because your client was what? 12 at the time?

MR. RZEPKA: (Indiscernible).

THE COURT: So why would a doctor use this procedure that contained a warning that it shouldn't be used in children and -- at least it wasn't determined whether it was -- it wasn't determined that it was appropriate in lumbar proceedings -- lumbar -- excuse me, in cervical spine procedures.

I mean, why would the doctor -- was the doctor ever sued?

MR. RZEPKA: Judge, the client felt that the doctor did a good job for the son and didn't want to involve him in any lawsuits. It was their choice.

THE COURT: Yeah, that just strikes me as kind of amazing. Now, I understand that maybe your theory now is, but I've precluded it, that your theory is that somehow that

Medtronic, Inc. knew from the testing they did that there was a danger using this in cervical spine procedures, at least that's kind of what the drift of your amended complaint, but that's not what you plead and what's before me.

You say that upon information and belief, the bone graft was used only for those specific applications, not only for those specific applications, but instead the defendant encouraged the medical industry to use the bone graft off-label in cervical spine procedures.

Well, that's -- even assuming you buy the conclusory they could do that, right? The medical -- there's nothing wrong with doing that. They could -- it would be up to the doctor whether to use it.

You also indicate in paragraph 8 the bone graft was defectively designed and manufactured. The details failed to warn the plaintiff and others of the dangers associated with using the bone graft especially -- especially off-label in cervical spine procedures.

There's a case that's pretty close on point that Mr. Kehoe found and that is Wisher -- maybe it was cited -- vs. Medtronic.

MR. RZEPKA: That would be *Swisher,* Your Honor.

THE COURT: Pardon?

MR. RZEPKA: It's *Swisher*, I believe.

THE COURT: Yes. Because I'm looking at -- it says

in pertinent part, because there was the issue of assertion -- it says plaintiff's claims for strict liability failure to warn, strict liability design defect and negligent failure to warn, all seek to impose safety related requirements on the device or its labeling beyond those expressed by the FDA. Accordingly, those claims are expressly preempted under 360(1)(a).

To the extent her claim for strict liability manufacturing defect is not preempted, her assertion of a manufacturing defect is wholly conclusory and, therefore, must be dismissed.

That's exactly -- I mean, again, to the extent you come under this, you know, parallel exception, it's conclusory. The bone graft was defectively -- I mean, really, you say it's defectively manufactured.

So I mean, it appears what you were trying to plead is some kind of fraud action, that Medtronic, Inc. fraudulently held back from the FDA concrete information that it had that the fusion material would, in fact, be harmful if used in cervical procedures.

But that's not pled in the complaint that I have before me, so, you know, based on what I can consider, I'm going to grant the application to dismiss.

However, I'm not going to dismiss it with prejudice because I don't know if you could plead an action. I don't

know if there's some manufacturing defect that could be pled.

I mean, I just don't know. What you pled is conclusory.

MR. TAUBER: May I be heard, Your Honor?

THE COURT: Yeah.

MR. TAUBER: Your Honor, I would -- I'd appreciate that, thank you.

I would encourage the Court to look at the proposed amended complaint that plaintiff's tendered that this Court struck for lack of timeliness.

Your Honor, I think in addition to any timeliness issue, if the Court looks at the complaint it will see that even the proposed amended complaint fails to state a cognizable claim for a variety of reasons, which we certainly could detail.

But --

THE COURT: But I can't -- I really can't -- I mean, I can't consider because I'm granting -- you asked me not to consider.

MR. TAUBER: Actually, Your Honor struck that before we had a chance to respond to this.

THE COURT: Well, no. I have a letter -- let me just make sure I have it. Plaintiff has not explained to the Court why he did not comply with the Court's scheduling order and filed his opposition when it was due on March 13th.

Medtronic has been prejudiced by plaintiff's failure to comply since he waited until after receiving Medtronic's reply before contacting the Court and seeking an extension of the time.

MR. TAUBER: I believe we go on to say should the Court wish to consider it, then we ask for an opportunity to respond, which was then obviated by the Court subsequently.

But I'm really not trying to hang anything on procedural nicety, it's more as a matter of substance plaintiff has asserted in the, albeit late -- albeit late, tendered opposition to Medtronic's motion, that they have now alleged everything that they can possibly allege that's stated in the opposition.

And so I don't think there would be any purpose served by allowing plaintiffs yet another bite at the apple. They have tendered a proposed amended complaint, which they say contains everything that they are able to allege.

And if the Court were to look at that complaint, I think the Court would readily conclude that even as pleaded in the proposed amended complaint, plaintiff fails to state a cognizable claim.

Both --

THE COURT: Let me put you on the spot.

MR. TAUBER: Yes.

THE COURT: Are you withdrawing your request that

I -- I interpreted that you were requesting that the Court not consider or grant the request to file papers late?

Because the only way I can do what you're asking me to do is if I can consider -- so I render a decision. I've already said I'm not going to consider the papers.

If you're saying that you believe you're going to prevail if the Court considers the paper because I would -- what you're asking me to do is say, all right, I'm going to consider the papers, and you believe if I do, I would deny the motion to amend on futility grounds.

MR. TAUBER: I do -- I do believe --

THE COURT: Is that what -- but to do that you have to tell me that, okay, we've reconsidered this and are withdrawing our opposition to plaintiff's request to file late.

You can't have it both ways.

MR. TAUBER: Your Honor, I hope you don't think I'm being too cute, I'm really not trying to be too cute.

Your Honor, the application that I was specifically making to the Court would be to stand by the Court's previous ruling not to consider, but to -- and any order that issues today say, had the Court considered that proposed amended complaint, had it been timely filed in proper procedural form it, nevertheless, would on the merits have denied that request for leave to amend because the complaint is futile, both

because it still does not satisfy Rules 8 or 9; and because it -- the claim stated --

THE COURT: But anything -- even if I -- let's talk about dismissal with prejudice. I would essentially have to say -- and there are situations where lawyers fail in their first two attempts to plead a complaint.

So I would essentially have to say that, listen, there's no cause that you could possibly plead. So even though -- even though your allegations -- it appears from the case that you're familiar with that you can have this kind of parallel action for defective manufacturing claim, at least that's what the Court is here saying.

The Court is saying in this case, to the extent her claim for strict liability manufacturing defect is not granted, there certainly can be a situation where it's not preempted, assertion of a manufacturing defect is wholly conclusory and must be dismissed for failure to state a plausible claim.

So, again, I could review the amended complaint. I can say it's futile. But then to dismiss with prejudice, I have to say, listen, there's no way you could possibly plead this claim, even -- it's conclusory again, but I don't know whether there's a defect in manufacturing.

MR. TAUBER: It's -- it's certainly the case, Your Honor, that a claim, not this claim, but a claim could in

theory state a manufacturing defect claim that avoided express preemption of Section 360k(a) if that plaintiff were able, consistent with Rule 11 and all the other Federal Rules, to plead facts sufficient under Rule 8 and *Twombly* that would, if true, establish that the manufacturing process of the device that that particular plaintiff received deviated in some manner from the process that the FDA had approved through the premarket approval process; and sufficient facts to establish that such purported deviation was a causal factor in the plaintiff's alleged injuries.

I do not believe that plaintiff in this case can, consistent with Rule 11 and the other pleading rules, make any such allegation.

THE COURT: But I don't know that. I mean, that's -- that's -- hasn't plaintiff at least suggested in his amended complaint that your client held back information that the use of the infusion material in cervical procedures was harmful --

MR. TAUBER: Yes, Your Honor. But the proposed amended complaint certainly has --

THE COURT: -- so --

MR. TAUBER: -- there are two -- if I may, Judge? There are two ways that allegation could be read. I desperately tried to tease out which two the plaintiff planned -- I wasn't sure, but one way in that -- in which it

could be read, I think this is the way in which it is meant, is that Medtronic is alleged to have withheld information --

THE COURT: -- from the FDA.

MR. TAUBER: -- from the FDA during the premarket approval process. In other words, prior to the grant of premarket approval. And that somehow the withholding of such information -- I'm not sure what the theory is exactly, but caused the FDA to grant approval which then ultimately led to plaintiff's injuries, something along those lines.

Now, that sort of claim, the claim that Medtronic or any device manufacturer withheld information from the FDA during the approval process is squarely precluded by the United States Supreme Court decision in *Buckman vs. Plaintiff's Litigation Committee,* I think it's called.

THE COURT: What -- let me just -- let me -- let me just read this line from the Second Circuit case.

MR. TAUBER: Yes.

THE COURT: We need not decide whether plaintiff's broad claims, because that's premised on allegedly misleading off-label promotion are preempted because, like the District Court, we conclude that these claims are not pleaded with particularity required under -- so this case was decided in --

MR. TAUBER: May, I believe, Your Honor.

THE COURT: -- this case --

MR. TAUBER: June, it came down in June. The

decision was granted by the Second Circuit on June 9th.

THE COURT: Okay. So what is --

MR. TAUBER: Does the fraud claim --

THE COURT: -- what does this mean, though? I read that and say the Second Circuit is saying, okay, a fraud claim could -- again, the language is we need not decide whether plaintiff's fraud claim's premised on allegedly misleading off-label promotions are preempted.

What does that mean? They could be preempted or there could not be preempted?

MR. TAUBER: As we -- as the -- Your Honor will note the cliff note that follows from that, the Second Circuit says the wave of authority both in this circuit and elsewhere cast doubt of liability of such claims.

So I think the court there is certainly signaling that it probably, had it had cause to reach it, it would have said no, they're not liable.

But just as a factual matter, Your Honor, I -- I argued both -- *Swisher* both in the District Court and also in the Second Circuit so I am familiar with the case.

The fraud claims that are being discussed there are claims based on purported representations or omissions after FDA approval, not prior to FDA approval.

Because the claimants there fully realized that any claim based on fraud on the FDA during the approval process is

squarely foreclosed by 21, U.S.C., Section 337(a) as interpreted by the U.S. Supreme Court in the *Buckman* decision.

That was a case squarely upholding that private claimants may not bring claims predicated on purported fraud on the FDA.

So if the claim in this case is that Medtronic withheld information from the agency during the premarket approval process, that claim is plainly futile under *Buckman* and 337(a).

If, on the other hand, the claim were that Medtronic failed to file adverse event reports with the FDA subsequent to the grant of premarket approval, there would be a slightly different analysis.

Bottom line, I think it's still preemptive and still fails under *Buckman* and 337(a), but I just want to acknowledge that it's slightly different --

THE COURT: What's the remedy if that happened?

MR. TAUBER: The remedy if that happened and --

THE COURT: When you --

MR. TAUBER: -- since -- individual citizen has no right to bring an action to enforce the FDCA. That is the import of 21, U.S.C., Section 337(a).

If a citizen believes that a manufacturer has violated provisions of the FDCA, that citizen may file a citizen's petition with the FDA, who then has the authority to

pursue civil, criminal, conjunctive and other relief against the manufacturer, so should a violation of the FDCA be established, you know, after investigation by the agency.

There is no doubt, Your Honor, that the preemption doctrine has the effect of depriving purportedly injured plaintiffs of legal remedies that they would otherwise have, and that is the effect of the preemption doctrine. It says notwithstanding the existence of an otherwise cognizable state law claim, which may or may not exist, that claim will not be recognized because federal law trumps that claim.

And in the *Riegel* decision, which is the seminal decision in this area from the U.S. Supreme Court, the court openly speaks of this and says clearly people -- some people will be left without judicial remedy, but that is the statutory scheme that Congress has adopted.

And in the recent decision by the Tenth Circuit, again, in a infuse related case, *Caplinger* presented the court the same notices of authority that we brought *Swisher* to the Court's attention. The Tenth Circuit also gives an extended explanation of why it not only is the law that such plaintiffs are preempted, but why it was rational for Congress to do that.

And so the remedy might not be compensatory damages awarded to plaintiff in a tort action, but there is ample enforcement authority vested in the FDA to pursue and act upon

perceived violations of the --

THE COURT: What about -- what about -- help me out. Why is the exception carved out for products liability based on defective manufacturing?

MR. TAUBER: It's not. It's -- it's somewhat different, Your Honor. The -- the relevant statute is 21, U.S.C., Section 360k(a) which prohibits any state from imposing or enforcing any requirement that is different from or in addition to the requirements imposed upon a device that received premarket approval through the -- from the FDA.

So the manufacturing defect, the hypothetical manufacturing defect plaintiff discussed before would or could escape express preemption under 360k(a) because it would allege that the manufacturer did not follow the requirements proposed on the device by the FDA through the premarket approval process, and that federal violation caused the damages. And, moreover, it rests on a state law requirement that is identical to the federal requirement.

So the federal requirement is from the FDA, you must manufacture the device in the certain way that's specified.

The federal -- the state law requirement is you must not build and sell a defective -- defectively manufactured product. Your failure to manufacture according to the FDA's specification is the very defect.

And so the state law requirements do not have that defect, the federal law requirements do not have that defect, are identical and, therefore, parallel claims within the meaning of *Riegel* and Section 360k(a).

Similarly, plaintiff here alleges failure to warn. If plaintiff alleged that Medtronic had failed to provide plaintiff's surgeon with the FDA mandated warning label and that that failure then caused the plaintiff's alleged injuries, that's a claim that could escape express preemption under 360k(a) for the exact same reason: There's a federal requirement to give these warnings, a state law requirement to give what would be adequate warnings, and the failure to fulfill those identical duties led to the injury.

That claim could escape express preemption. But there is no, and as far as I know, can be no allegation in this case that Medtronic failed to supply --

THE COURT: Let me just go back and ask you a question because it's instructive. So if Medtronic -- if Medtronics before FDA approval held that information -- testing information that showed that using the infusion material in cervical procedures could be dangerous, again, help me out, that is preempted?

MR. TAUBER: That would be -- any claim based on withholding information from the FDA during the approval process is preempted -- impliedly preempted to be clear,

impliedly preempted under 21, U.S.C., Section 337(a) and Supreme Court's decision in *Buckman*.

If I can just give --

THE COURT: No, but then if -- if after approval Medtronics did further research and found that the use of the infusion material in cervical procedures is dangerous after the approval, that could be the basis for, or could it not? Because you made that distinction.

MR. TAUBER: I think it would be more -- to ask the hypothetical usefully, Your Honor, because there are certain federal requirements with respect to post approval reporting. I think that's what the plaintiff tries to tie their hat around.

That's very specific. It's not about research. It's about if the manufacturer becomes aware of certain administratively defined adverse events, then the manufacturer has an obligation to submit reports, adverse event reports to the FDA, again, under certain specific circumstances.

So there is a post approval reporting requirement, which is codified or at least the regulation is codified at 21, C.F.R, Section --

THE COURT: So that's -- those -- those claims are preempted too?

MR. TAUBER: Those claims are preempted too both expressly and impliedly because the federal duty is a duty to

submit an administrative report to the FDA.

The closest state law analogue that one could find would be a failure to warn the physician. But those two duties are not identical. On the one hand, it's a duty to report to the FDA under federal law; and on the other hand it's a duty to warn physicians.

But federal law does not require the provision of adverse event reports to physicians. And state law does not require the reporting of anything to the FDA.

If I could, Your Honor, I would like to point to a New York State case, which is squarely on point, and that is *Lake vs. Kardjian*, that's K-A-R-D --

THE COURT: Let me just get this up, if you will. Okay, give me the cite, please.

MR. TAUBER: Yes, 874 --

THE COURT: 874.

MR. TAUBER: N.Y.S. 2d at --

THE COURT: N.Y. --

MR. TAUBER: N.Y.S. 2d at 755 pin cite, Your Honor.

THE COURT: So 874 N.Y.S. 2d.

MR. TAUBER: At 755.

THE COURT: Let me see if I can get there.

MR. RZEPKA: It's N.Y.S. 2d. N.Y.S. --

MR. TAUBER: N.Y.S. 2d, yes.

MR. RZEPKA: It's 755 cited case was --

(indiscernible).

THE COURT: That's *Lake vs.* --

MR. TAUBER: *Kardjian*.

THE COURT: Got it. Okay.

MR. TAUBER: And at page 755, the New York State Court states that the alleged failure to comply with the MDA, its medical class defendants, reporting requirements does not constitute a parallel claim.

THE COURT: Let me throw out to you, Mr. Rzepka, I mean the issue -- the only issue to me is whether I dismiss it with or without prejudice.

Mr. Tauber has mentioned Rule 11 and suggests that you really can't plead -- even if it was dismissed without prejudice and assuming you're within the statute of limitations, he is -- I was going to say suggesting, but he's not suggesting, he's saying, he's representing that you can't, consistent with Rule 11, plead any claim because either you don't have it or it's -- or it's preempted.

Do you have information -- do you have proof that Medtronics, before we even get to the preemption issue, that Medtronics held back information from the FDA?

MR. RZEPKA: Judge, I have no information at this time. It would be subject to discovery, but I have none, to be quite frank with the Court.

THE COURT: So where are you going with this case?

Even if I dismissed it without prejudice, where are you going? You still would have to -- all that means is we don't get to discovery unless you plead a viable claim.

Is he right on his preemption argument that you're preempted? He's essentially saying that -- that you're preempted. The only parallel action you could claim is that if Medtronics didn't warn the user, by "the user" I mean the doctor and there's no proof of that.

In fact, the proof is just to the contrary. The doctor, whoever performed the surgery, did so despite the warning that it shouldn't be used on children -- let's just start with that. It shouldn't be used on children and he did it anyway.

Did anybody ever -- did he ever explain why he did that?

MR. RZEPKA: Not that I am aware of, Judge, no.

THE COURT: So what is your position knowing that you have a Rule 11 obligation, knowing that if I granted -- if I dismissed it without prejudice, it only means that if you're within the statute of limitations you could refile.

Is there anything you can plead?

MR. RZEPKA: Judge, I don't think I am within the statute anyway.

THE COURT: Pardon?

MR. RZEPKA: I don't think I'm within the statute.

If it was a fraud cause of action, but what's -- (indiscernible) on these things, but if what he says is true and it is preempted even on a fraud, again with the statute of limitations -- take discovery on that, but I wouldn't have a claim that would be within the statute.

THE COURT: Well, then the Court is inclined to dismiss it with prejudice. There's nowhere you can -- what you seem to be telling me is even if I didn't -- you have no indication that Medtronics held back adverse reports, that you have really no indication of any kind of, assuming it wasn't preempted, you have no indication of -- I don't know how you manufacture -- there would be a manufacturing defect.

So you have no -- and I appreciate your candor. You're telling me you have no -- really no basis to go anywhere with this lawsuit.

MR. RZEPKA: Judge, I really don't.

THE COURT: All right, thank you very much. I am going to grant the application to dismiss.

Thank you, counsel.

(**WHEREUPON**, the proceedings adjourned at 2:35 p.m.)

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CERTIFICATE OF REPORTER

In accordance with 28, U.S.C., 753(b), I certify that these original notes are a true and correct record of proceedings in the United States District Court for the Western District of New York before the Honorable Charles J. Siragusa on September 10, 2015.

S/ Christi A. Macri

Christi A. Macri, FAPR-CRR
Official Court Reporter